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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,665	09/23/2003	Jean-Claude Yvin	16721-0240 (42528-292744)	1061
881	7590	10/21/2005	EXAMINER MAJER, LEIGH C	
STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			ART UNIT 1623	PAPER NUMBER

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/668,665

Applicant(s)

YVIN ET AL.

Examiner

Leigh C. Maier

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 July 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/14/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-10, with cancer/tumor as the elected disorder species in the reply filed on July 22, 22005 is acknowledged.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling the treatment of cancer with higher molecular weight (mw) oligosaccharides or lower mw oligosaccharides in combination with other agents (See art discussed below), does not reasonably provide enablement for the treatment of cancer with a lower mw oligosaccharide as a single entity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification presents no data involving direct treatment of a tumor or cancerous condition. Applicant appears to rely on an immunological mechanism wherein administration of said glucans induces the production of tumor necrosis factor (TNF), as discussed at page 10 of the instant specification. However, the action of TNF in the tumor microenvironment is highly unpredictable. In many cases, this cytokine has pro-cancer activity.

Art Unit: 1623

See Balkwill (Cytokine Growth Fact. Rev., 2002) at section 3. Furthermore, Cavallo et al (Exp. Opin. Biol. Ther., 2005) discusses the state of the art (years after the current filing date) regarding the use of immunomodulatory agents that result in a downstream induction of cytokines. See section 2.3, 3<sup>rd</sup> paragraph. This type of therapy has resulted in very limited success.

Although the level of skill in the art would be expected to be high, the use of an agent whose purported mechanism is the induction of increased TNF levels remains unpredictable. Therefore one of ordinary skill would require undue experimentation, especially with no suggested dosages or particular protocols disclosed, to use the invention commensurate with the scope.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by YVIN et al (WO 99/39718).

YVIN discloses the method the treatment of disorders resulting from apoptosis dysfunction comprising the administration of  $\beta$ -glucan oligosaccharides. The reference describes cancer as one such disorder. See reference claim 8 and the paragraph bridging pages 3 and 4. The

Art Unit: 1623

activities recited in claims 5 and 6 are inherent activities that would result from the administration of the oligosaccharide whether or not it was recognized in the original reference.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-7, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over YVIN et al (WO 99/39718) in view of HILLMAN et al (US 5,858,715).

YVIN teaches as set forth above. The reference is silent regarding particular types of cancer.

Art Unit: 1623

HILLMAN teaches the treatment of diseases comprising impaired apoptosis. These include a variety of cancers, such as lung, breast, ovarian, and colon. See abstract and col 16, lines 43-53.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the recited oligosaccharides to treat the cancers taught by HILLMAN to comprise decreased apoptosis. One of ordinary skill would reasonably expect success in such treatment because YVIN had taught that the oligosaccharides have utility in such treatment. It would further be within the scope of the artisan to select any appropriate method of administration with routine experimentation.

Claims 1 and 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over YVIN et al (WO 99/39718) in view of PENNEY et al (US 5,688,771).

YVIN teaches as set forth above. The reference is silent regarding the use of other therapeutic agents in combination with the oligosaccharides.

PENNEY teaches the use of immunodulatory peptides, alone, or in combination with chemotherapeutic agents for the treatment of cancer.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer the oligosaccharides taught by YVIN in combination with an immunomodulatory agent and/or a chemotherapeutic agent. Given that all these agents are known to have utility in for the treatment of cancer, the artisan would be motivated to administer them in combination for their combined effects. It would further be within the scope of the artisan to select any appropriate method of administration with routine experimentation.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5-7 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 14 of U.S. Patent No. 6,750,208.

Although the conflicting claims are not identical, they are not patentably distinct from each other. The reference claim is drawn to the treatment of apoptosis dysfunctions by the administration of  $\beta$ -glucan oligosaccharides. The specification describes apoptosis dysfunctions as comprising cancer. See col 2, lines 27-31. Therefore, it would have been obvious to one having ordinary skill to administer said oligosaccharides for the treatment of cancer. It would be within the scope of the artisan to select any method of administration through routine experimentation.

Claims 1-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 10 of copending Application No. 10/698,034. Although the conflicting claims are not identical, they are not patentably distinct from each other. The reference claims are drawn to the administration of oligo- $\beta$ -glucans, including the tetraoligosaccharide or pentasaccharide for the treatment of

Art Unit: 1623

cancer. The reference claims further recite the same types of cancer and the further administration of a potentiator in a variety of forms.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. It is noted that while the claims have not issued, they have been allowed.

*Examiner's hours, phone & fax numbers*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-930692.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more. Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov> Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

*Leigh C. Maier*

Leigh C. Maier  
Primary Examiner  
October 17, 2005